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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,858	03/31/2004	Rakesh Tuli	U 015125-9	5596

7590

07/15/2005

Ladas & Parry  
26 West 61st Street  
New York, NY 10023

EXAMINER
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MARVICH, MARIA

ART UNIT	PAPER NUMBER
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1633

DATE MAILED: 07/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/814,858

**Applicant(s)**

TULI ET AL.

**Examiner**

Maria B. Marvich, PhD

**Art Unit**

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 31 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/24/05</u> . | 6) <input type="checkbox"/> Other: ____.  |

Art Unit: 1633

### **DETAILED ACTION**

Claims 1-10 are pending in the application.

#### ***Information Disclosure Statement***

An IDS filed 1/24/05 has been identified and the documents considered. The signed and initialed PTO Form 1449 has been mailed with this action.

#### ***Specification***

The disclosure is objected to because of the following informalities: several misspellings were found on page 9. The word "te" in line 3 should be "the". The word "bases" in line 32 should be "basis". The word "from" in line 33 should be "form"

Appropriate correction is required.

#### ***Claim Objections***

Claims 1 and 10 are objected to because of the following informalities: the word "upto" should be written as two words "up" and "to". Appropriate correction is required.

#### ***Double Patenting***

Claim 10 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 2. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim

Art Unit: 1633

to object to the other as being a substantial duplicate of the allowed claim. See MPEP

§ 706.03(k).

***Claim Rejections - 35 USC § 112, first paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to a bidirectional promoter comprising a sequence shown in SEQ ID NO:1 and SEQ ID NO:2 or up to 70% homologous of each. Thus applicants claim a genus of bidirectional promoters that are comprised of a genus of sequences up to 70% homologous to SEQ ID NO:1 and a genus of sequences up to 70% homologous to SEQ ID NO:2 as well as a genus of promoters that comprises each genus of sequences.

The written description requirement for genus claims may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with known or disclosed

Art Unit: 1633

correlations between function and structure, or by a combination of such characteristics sufficient to show that the applicant was in possession of the claimed genus.

The instant invention is drawn to a bi-directional promoter comprising two separately chemically synthesized and strategically designed artificial sequences, a Transcription Activation Module, depicted in SEQ ID NO:1, and a Transcription Initiation Module, depicted in SEQ ID NO:2. Furthermore, the claims recite that the bidirectional promoter can be comprised of sequences up to 70% homologous to TAM and to TIM. Applicants only exemplify the synthesis of sequences that are equivalent to those depicted in SEQ ID NO: 1 for TAM and SEQ ID NO:2 for TIM. An adequate written description of the invention defined by the claims requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is the knowledge in the prior art and/or a description as to the availability of a representative number of species of claimed nucleic acid sequences. Applicants claim a large genus of sequences that are up to 70 % homologous with TAM and/or TIM. However, applicants have not provided structural information that would demonstrate what the structural requirements of TAM and TIM are such that a bidirectional promoter can be identified from the large genus of sequences. In addition, claiming all sequences up to 70% homologous to SEQ ID NO: 1 or SEQ ID NO: 3 that achieve a result without defining what means will do so is not in compliance with the written description requirement. Rather, it is an attempt to preempt the future before it has arrived. (See *Fiers* 7. Revb 25 USPQZd 1601 (CA FC 1993) and *Regents of the Univ. Calif v. Eli Lilly & Co.* 43 USPQZd 1398 (CA FC, 1997)). In the instant case, applicants have defined two sequences that in conjunction generate a bidirectional promoter. However, applicants have not demonstrated that variance of any up to 30% of the

Art Unit: 1633

nucleotides would result in a promoter that can function similarly. Therefore, the relationship between structure and function is unclear as neither applicant nor the prior art provide a correlation between the structures of TAM and TIM and the ability to promoter bidirectional expression. Given the large size and diverse nature of the recited sequences and the inability to determine which will also possess the ability to mediate bidirectional expression, it is concluded that the invention must be empirically determined. In an unpredictable art, the disclosure of TAM and TIM would not represent to the skilled artisan a representative number of species sufficient to show applicants were in possession of claimed genus.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in that the metes and bounds of the promoter are unclear. The description comprises parts a) and c). However, it is unclear if part b) is missing or there is no part b).

Claim 10 is vague and indefinite in that the metes and bounds of the promoter are unclear. The description comprises parts c), d) and c). It is unclear what is intended by the designation as there is no apparent order to their usage.

#### ***Claim Construction***

Art Unit: 1633

The specification teaches that TAM can activate transcription in either or both direction when a second DNA component called TIM is placed in either or both directions (see e.g. page 6, lines 9-4). Therefore, the actual occurrence of TIM on either side of TAM generates a bidirectional promoter. Given that Tam and Tim in strategic positions is found in the art as demonstrated below, applicants appear to be reciting a new function for an old product. The promoters inherently are bidirectional as they meet the requirements of the bidirectional promoter as described by the instant specification.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1- 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Sawant et al (Theor Appl Genet, 2001, Vol 102, pages 635-644 as evidenced by pUC19; see entire document).

Sawant et al teach a promoter comprising a sequence corresponding to SEQ ID NO:1, TAM, and a sequence corresponding to SEQ ID NO:2, TIM, as recited in claim 1 (see e.g. figure 1). The Tim is located 5' to 3' in a position corresponding to "either side" of Tam, which is also placed 5' to 3' as recited in claims 2-4 and 10. The promoter, Pcec, was inserted in pUC19 and

Art Unit: 1633

with gusA as recited in claim 5 (see e.g. page 636, bridging paragraph col 1-2). As evidenced by the pUC19 map, insertion of Pcec into the vector would result in a selection marker in one direction with gusA in the opposite as recited in claim 9. TAM was placed within -100 to -500 and TIM within -100 of the transcription initiation site as recited in claims 6 and 7 (see e.g. figure 1). The constructs were stably transformed into plants as recited in claim 8 (see e.g. page 637, col 2, paragraph 2).

Claims 1-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Tuli et al (US 6,639,065 B1; see entire document) as evidenced by pUC19; see entire document).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Tuli et al teach a promoter comprising a sequence corresponding to SEQ ID NO:1, TAM, and a sequence corresponding to SEQ ID NO:2, TIM, as recited in claim 1 (see e.g. figure 1). The Tim is located 5' to 3' in a position corresponding to "either side" of Tam, which is also placed 5' to 3' as recited in claims 2-4 and 10. The promoter was inserted into pUC19 with a reporter gene, uidA, as recited in claim 5 (see e.g. col 12, line 38-60). As evidenced by the pUC19 map, insertion of the synthetic promoter into the vector would result in a selection marker in one direction with uidA in the opposite as recited in claim 9. The synthetic promoter-



Art Unit: 1633

uidA construct was stably transformed into plants as recited in claim 8 (see e.g. col 14, line 4-39). The promoter was placed with uidA such that TAM was within -100 to -500 and TIM was within -100 of the transcription initiation site as recited in claims 6 and 7 (see e.g. col 12, line 38-60).

### *Conclusion*

No claims allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B. Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (571)-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maria B Marvich, PhD  
Examiner  
Art Unit 1633

July 8, 2005

  
Daniel M. Sullivan  
Patent Examiner